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10/552,951	06/22/2006	William F. Ogilvie	81723	6894
22342	7590	04/29/2008	EXAMINER	
FITCH EVEN TABIN AND FLANNERY			LEVINI, JOSHUA H	
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04/29/2008 PAPER				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,951	<b>Applicant(s)</b> OGILVIE, WILLIAM F.
	<b>Examiner</b> JOSHUA LEVINE	<b>Art Unit</b> 4177

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 June 2006.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08),  
 Paper No(s)/Mail Date 11/27/2007/6/29/2006.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 5-7, 9-10, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Klawitter (5645605).

3. Regarding claim 1, Klawitter disclosed a prosthesis for a CMC joint comprising a circular disk 16 (figure 4) having convex spherical surfaces and an axial hole defined by diameter 20 and convex spherical surfaces being interconnected by a curved rim surface (figure 4).

4. Regarding claim 2, Klawitter disclosed an axial flaring hole defined by diameter 20 is a section of a torus. The axial hole of diameter 20 comprises the center section of a torus (column 4 lines 20-23).

5. Regarding claim 5, Klawitter disclosed an implant where the pair of convex spherical surfaces was the same. The disk was made by a revolved circle, the circle

inherently having a constant radius and therefore resulting in a torus with identical surfaces (column 4 lines 20-23).

6. Regarding claim 6, Klawitter disclosed an implant where the convex spherical surface is at least about twice the radius of said circular disk and wherein said peripheral rim surface is a segment of a sphere. The disk radius 22 and the hole radius 20 have equal measurements (column 4 lines 20-23). Therefore, the radius of the curvature of the disk is three times circular disk radius 22 (see Figure A)

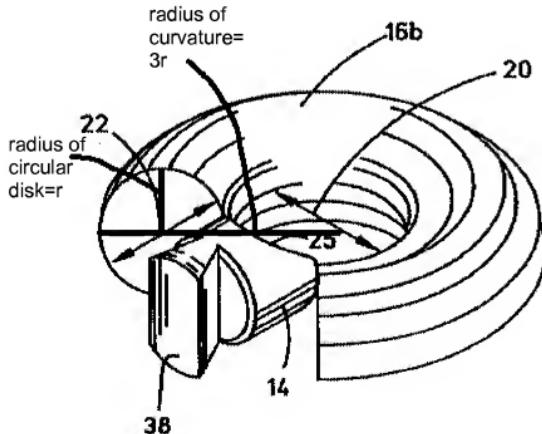


Figure A from labels and dimensions the radius of the disk and the radius of curvature

7. Regarding claim 7, Klawitter disclosed resecting the base of the metacarpus (column 5 lines 58-63) and the distal surface of the trapezium (column 6 lines 16-19) to provide surfaces which match the surfaces of the implant, creating passageways (column 5 line 60) by hollowing out the intermedullary canal in the metacarpus and

forming a cavity in the trapezium (column 6 line 18) opening into said resected concave surfaces, and surgically implanting the metacarpal element (column 6 lines 3-6) and fitting the base of the trapezium element into bone (column 6 lines 35-37).

8. Regarding claim 9, Klawitter disclosed a CMC joint prosthesis comprising a circular disk 16 (figure 4) having convex spherical surfaces and an axial hole defined by diameter 20 and convex spherical surfaces being interconnected by a curved rim surface.

9. Regarding claim 10, Klawitter disclosed an axial flaring hole defined by diameter 20 is a section of a torus. The axial hole of diameter 20 comprises the center section of a torus (column 4 lines 20-23).

10. Regarding claim 13, Klawitter disclosed an implant where the pair of convex spherical surfaces was the same. The disk was made by a revolved circle, the circle inherently having a constant radius and therefore resulting in a torus with identical surface having a peripheral rim surface of a sphere (column 4 lines 20-23).

11. Regarding claim 14, Klawitter disclosed an implant where convex spherical surface is at least about twice the radius of said circular disk and wherein said peripheral rim surface is a segment of a sphere. The disk diameter 22 and the hole diameter 20 have equal measurements, (column 4 lines 20-23). Therefore, the diameter of the curvature of the disk is three times circular disk diameter.

12. Claims 1-3, 9-11 are rejected under 102(e) as being anticipated by Bryan et al (PG Pub No.20020035400).

13. Regarding claim 1, Bryan disclosed a disk 60 (figure 7) having convex spherical surfaces and an axial hole 98 (figure 8) and the convex spherical surfaces being interconnected by a curved rim surface.

14. Regarding claim 2, Bryan disclosed an implant with an axial flaring opening that is a section of a torus (figure 7, paragraph 96)

15. Regarding claim 3, Bryan disclosed an implant where the radius of curvature between the transition surface of the convex sphere is about 15% to about 30% less than the height of the disk (about 33% as given by the values of b=30, and c=10 for the quadratic surface as disclosed in paragraph 94)

16. Regarding claim 9, Bryan disclosed a circular disk 60 (figure 7) having convex spherical surfaces and an axial hole 98 (figure 8) and the convex spherical surfaces being interconnected by a curved rim surface.

17. Regarding claim 10, Bryan disclosed an implant with an axial flaring opening that is a section of a torus (figure 7, paragraph 96)

18. Regarding claim 11, Bryan disclosed an implant where the radius of curvature between the transition surface of the convex sphere is about 15% to about 30% less than the height of the disk (about 33% as given by the values of b=30, and c=10 for the quadratic surface as disclosed in paragraph 94)

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (PG Pub No.20020035400) in view of Ateshian et al (6126690).
21. Regarding claim 4, Bryan disclosed of the limitations of the claim except for a radius of curvature of the transitional surface being between .7 mm and about 3 mm. Ateshian teaches a system for designing metacarpal joints using measurements from .7mm to about 3 mm (column 12 lines 21-24). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the reference of Bryan to include convex spherical radii measuring from .3mm to 3.00 mm, as suggested and taught by Ateshian, for the purpose of making articular surfaces that are highly accurate in shape as conform to individual anatomies (column 5 lines 41-45).
22. Regarding claim 12, Bryan disclosed of the limitations of the claim except for transitional surfaces between the torus and convex spherical surfaces being between .7 mm and about 3 mm. Ateshian teaches a system for designing metacarpal joints using measurements from .7mm to about 3 mm (column 12 lines 21-24). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the reference of Bryan to include convex spherical radii measuring from .3mm to 3.00 mm, as suggested and taught by Ateshian, for the purpose of making articular surfaces that are highly accurate in shape as conform to individual anatomies (column 5 lines 41-45).

23. Claims 8 and 17 are rejected under U.S.C. 103(a) as being unpatentable over Klawitter (5645605) in further view of Klawitter et al (6159247).

24. Regarding claims 8 and 17, Klawitter (5645605) disclosed all the elements of the claim except for selecting an implant to be implanted from a set of said implants of different sizes. Klawitter et al. (6159247) teaches a metacarpal joint that comes in a variety of sizes from which to choose (column 6 lines 8-11). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the reference of Klawitter (5645605) to include the set of implants of different sizes, as suggest and taught by Klawitter et al (6159247), for the purpose of accommodating joints of different sizes.

25. Claims 15-16 are rejected under U.S.C. 103(a) as being unpatentable over Klawitter (5645605).

26. Regarding claim 15, Klawitter disclosed all the element of the claim except for resecting the base of the proximal bone of the digitus and the distal surface of the carpal or tarsal bone to provide concave surfaces which match the convex surfaces of the disk, creating passageways respectively in said bones which open into said resected concave surfaces, and surgically implanting the disk. Klawitter teaches this method for a different set of bones where he resects the base of the metacarpus (column 5 lines 58-61) and the distal surface of the trapezium (column 6 lines 16-19) to provide surfaces which match the surfaces of the implant, creating passageways (column 5 line 60) in the metacarpus and the trapezium (column 6 line 18) opening into said resected concave surfaces, and surgically implanting the metacarpal

element (column 6 lines 3-6) and implanting the prosthesis's base of the trapezium element into bone (column 6 lines 35-37). It would be obvious for one with ordinary skill in the art at the time of the invention to apply the resection method of the metacarpus and trapezium, as suggested and taught by Klawitter, for the purpose of implanting the prosthesis into a plurality of different types of joints.

27. Regarding claim 16, Klawitter disclosed all the elements of the claim, including resecting the base of the metacarpus (column 5 lines 58-61) and the distal surface of the trapezium (column 6 lines 16-19) to provide surfaces which match the surfaces of the implant (column 6 lines 34-37), creating passageways in the metacarpus (column 5 line 60) and the trapezium (column 6 line 18) opening into said resected concave surfaces, and surgically implanting the implant (column 6 lines 3-6, column 6 lines 35-37) that is circular disk 16 (figure 4) having convex spherical surfaces and an axial hole defined by diameter 20 and convex spherical surfaces being interconnected by a curved rim surface, except for the resected shape of the metacarpus having a the same spherical curvature of the circular disk. It would be obvious for one with ordinary skill in the art at the time of the invention to modify the reference of Klawitter to resect the metacarpus so as to have the same shape as the implant to allow for a more complimentary mating surface and better fixation of the prosthesis to the bone.

28. Claims 18-20 are rejected under U.S.C. 103(a) as being unpatentable over Klawitter (5645605) in further view of Swanson (4198712).

29. Regarding claim 18, Klawitter disclosed all the limitations of the claim except for a step of passing a flexible cord through the passageway created in the

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metacarpus, the flaring axial opening and the passageway created in the trapezium so that the flexible cord conforms to the flaring surface of the axial hole in the plane of flexion when each bone slides on the respective mating convex surface of the disk. Swanson teaches a method for repairing the joints in the wrist by passing a cord through a passageway 102 (figure 14) to stabilize the wrist and prevent dislocation (column 8 line 19-31). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the reference of Klawitter to include the flexible cord through the passageway created in the metacarpus, the flaring axial opening and the passageway created in the trapezium, as suggested and taught by Swanson, for the purpose of further stabilizing the implant inside the bone and inhibiting dislocation of said bone.

30. Regarding claim 19 Klawitter disclosed all the limitations of the claim except for flexible cord being a harvested tendon. Swanson discloses a flexible cord being a harvested ECRB tendon (column 8 lines16-19). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the reference of Klawitter to include the harvested tendon, as suggested and taught by Swanson, for the purpose of further stabilizing the implant inside the bone and inhibiting dislocation of said bone.

31. Regarding claim 20 Klawitter disclosed all the limitations of the claim except for a tendon harvested from the vicinity of the CMC joint where it remains attached and the free end is passed through said passageways and tied off or knotted. Swanson a method for harvesting an ECRB tendon 120 (figure 13) near the CMC joint and where

one end of the tendon stays attached (figure 13) and the other gets tied off (column 8 lines 29-30, figure 14). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the reference of Klawitter to include the harvested tendon from the vicinity of the CMC joint, as suggested and taught by Swanson, for the purpose of further stabilizing the implant inside the bone and inhibiting dislocation of said bone.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA LEVINE whose telephone number is (571)270-5413. The examiner can normally be reached on Monday-Thursday 7:30am-5:00pm ETA.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang Thanh can be reached on 571-272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L./  
Examiner, Art Unit 4177

/Quang D. Thanh/  
Supervisory Patent Examiner,  
Art Unit 4177